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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,691	10/17/2003	Balkrishen Bhat	20717YCA	4680

210 7590 02/03/2006

MERCK AND CO., INC
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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,691	BHAT ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/17/2003 (preliminary amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **1-21** have been cancelled, no claims have been amended, new claims **22-31** have been added, and the disclosure has not been amended as per the preliminary amendment filed October 17, 2003. One Information Disclosure Statement (1 IDS) filed January 20, 2004 has been received with all newly cited references and made of record.

Claims **22-31** remain in the case.

The disclosure is objected to because of the following informalities:

The first paragraph at page one of the disclosure has not been updated to include the issued patent which is a parent of the instant application.

Appropriate correction is required.

Claim **30** is objected to because of the following informalities:

In claim **30** at line 3, the term "compound of claim **27**" incorrectly implies that claims **27** is a compound claim. Examiner suggest the term should be amended to read -- compound defined in claim **27** -- .

Appropriate correction is required.

Claims **27-31** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed enabling exemplifications.

The definitions of the targets of medicinal action in claims **27-31** are directed to a vast number of specific disease conditions not all of which appear to have been tested as reported by the instant disclosure to determine whether any compound(s) defined by instant claim **27** actually have the desired medicinal effect. The disclosure states that compounds have been tested in some cases but fails to report which compounds, or what activities said compounds have, if any, against any one of the substantial array of different disease conditions listed at pages 20-21 of the disclosure.

In addition, the method of claims **30 and 31** is excessive in scope because the disclosure fails to include any completely described exemplifications disclosing the effect of the combinations of the anti-HCV compounds listed in the noted claims. No data appears to have been provided to support the conclusory language presented.

And lastly, claim **27**'s definition of the variables found in the generic structure at line 4 encompass a vast array of compounds because of the layers upon layers of substituents while the specific embodiments fails to provide the minimum requisite guidance necessary to make only a small fraction of these compounds. There are no specific embodiments which exemplify the layering of substituents permitted by the definitions of these variables. Examiner respectfully requests narrowing of the scope of the instant variable definitions to more nearly correspond to the scope of the specific embodiments actually synthesized.

Claims **27-31** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The subject matter of claims **27-31** are not fully enabled and undue experimentation is required. The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in In re Wands (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims is limited to the treatment of a variety of diseases in the *Flaviridae* and *Picorniviridae* families of viral infections with any single compound defined in claim **27**.

B. The nature of the invention is the treatment of any viral infection selected form either one of the *Flaviridae* and *Picorniviridae* families of viral infections with a compound defined in claim **27**.

C. The state of the prior art, as demonstrated by the Merck Manual (PTO-892 ref. **X**), is a description of symptoms, tests to determine the particular infection causing hepatitis symptoms, and administration of interferon to treat HCV.

D. The level of one or ordinary skill is indeterminate because the claimed invention represents a combination of chemical and medicinal technologies disclosed by doctorate level practitioners, but the technologies have not been completely described.

E. The level of predictability in the art is low because there is only one active ingredient (interferon) reported to be effective in the treatment of HCV by the Merck Manual.

F. The amount of direction provided by the inventor is limited to disclosure of the activity of individual compounds defined in claim **27** against HCV (only a conclusory statement, no specific data), but fails to disclose any exemplifications of the treatment of HCV with multiple active ingredients.

G. The existence of working examples is limited to those noted above and fails to include any wherein the HCV is shown to have been effectively treated with an individual active ingredient or with any combinations of multiple active ingredients.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure would be excessive because there is no guidance to direct the ordinary practitioner in seeking out the proper conditions which would lead to a protocol effective to treat an HCV infection with any single compound of claim **27**, let alone combinations of the individual compounds listed in claim **30**. The prior art disclosures referred to at page 47 et seq. are not seen to be a proper basis to argue against this rejection.

Claim **27** is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **27** at lines 8, 10, and 17, the term "alkyl is unsubstituted to substituted" suggests a logical inconsistency in the meaning of the team "alkyl." Examiner suggest replacement of the noted term with the term
-- alkyl is optionally substituted -- to avoid the implication that alkyl is anything but C_nH2_{n+1}.

A similar problem occurs in claim **27** at lines 21 and 27, wherein a similar solution applies (-- optionally substituted -- in place of "unsubstituted or substituted").

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **22-27 and 30-31** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-3 and 13*** of U. S. Patent No. **6,777,395** (PTO-892 ref. **A**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment of hepatitis C virus (HCV) and the active ingredients (pyrrolo[*2,3*-**d**]pyrimdine-5'-mono- and di-phosphates) are directed to substantially overlapping subject matter.

Claims **28 and 29** would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. §112 set forth in this Office Action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

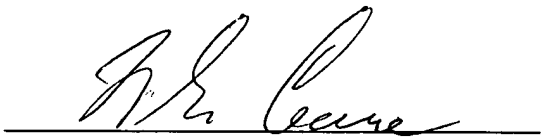
Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
01/29/2006



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